UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	MDL No. 2419 Master Dkt. 1:13-md-02419-RWZ
THIS DOCUMENT RELATES TO: All Cases Identified In Dkt. Nos. 1401, 1471, 1472, & 1473 and The PSC's Previous Response Dkt. No. 1518 & 1519	

THE PLAINTIFFS' STEERING COMMITTEE'S
OPPOSITION TO LIBERTY INDUSTRIES, INC.'S OMNIBUS MOTION FOR SUMMARY JUDGMENT IN CASES FILED BY PLAINTIFFS INJECTED IN INDIANA

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The Plaintiffs' Steering Committee respectfully submits this memorandum of law in opposition to the Motion for Summary Judgment[1] ("Motion") filed by Liberty Industries, Inc. ("Liberty" or "Defendant"). Plaintiffs have met their burden under Rule 56 of the Federal Rules of Civil Procedure and applicable case law. The Motion should be denied.

I. INTRODUCTION

Liberty Industries, Inc. ("Liberty") designed, manufactured, and installed the so-called "cleanrooms" NECC used to compound the contaminated products responsible for the death of at least 64 people and injury to hundreds, if not thousands, of others. Liberty's cleanrooms were designed, constructed and installed in a manner unsuitable for their intended use, resulting in the production of contaminated pharmaceutical that caused injury to Plaintiffs.

Liberty attempts to avert the Court's attention from its own failings in the design, installation and certification of the NECC cleanrooms to the failure of NECC to properly maintain the cleanrooms. A properly designed and built cleanroom is the first line of defense against contamination. Liberty's defective and unsuitable design, construction and installation, followed by its hasty certification of NECC's cleanrooms, created a facility with a high risk for contamination of products. Without Liberty's defective cleanroom design and/or installation, there may have been no contamination at all.

Liberty's negligence began with the decisions to build cleanrooms in the NECC warehouse without properly accounting for the constant changes in air pressure endemic to an old and drafty building. Constant changes in air pressure led to the movement of ceiling tiles above the work surfaces used to compound pharmaceuticals within the 2006 Cleanroom (also referred to herein as Cleanroom 1) allowing exposure from unfiltered contaminated air from

[1] ECF Nos. 1471-72

outside the cleanroom. Inspection of the ceiling of Cleanroom 1 from above shows evidence that the initial design of the ceiling grid – the pattern of interlocking inverted "T" shaped bars that hold ceiling tiles, light fixtures and HEPA filters in place – was not designed or installed properly such that gaps existed in the ceiling, some as wide as ¼ of an inch. These gaps allowed for particulate matter from above the cleanroom to rain down into the work space and contamination to infiltrate the pharmaceutical production areas. Some of these gaps occurred directly above the work spaces where drugs were compounded. Finally, Liberty failed to properly certify the operation of the cleanroom under the very standards it admits in its Motion it was obligated to meet.

II. STATEMENT OF FACTS

Because the production of pharmaceuticals for human consumption is such a sensitive process, well-functioning clean rooms are essential. The process requires both precision and the most sanitary conditions possible. A single fungus spore poses a serious threat to the safety of patients if it finds its way into a pharmaceutical intended to be injected into the epidural space of a human spine, knee, or any other body part.

A. Cleanrooms are designed to seal out contamination from outside the room.

A cleanroom is an isolated environmentally controlled production space that is specifically designed to prevent contamination.[2] Cleanrooms are most often designed for the purpose of controlling various forms of particulate contamination. Particulate contamination is pervasive in the air that we breathe and on the surface of every object that we encounter. The air we breathe typically contains more than 1,000,000 particles larger than 0.5 microns per every

[2] *See* Declaration of Dr. Philip J. Austin, Ph.D ("*Austin Decl.*"), ¶7, *Sobol Decl.*, Ex. 16.

cubic foot of air volume.[3] In a production environment (such as for pharmaceuticals) where contaminants pose a serious health risk, these contaminants must be eliminated or significantly reduced.[4] Proper cleanroom design, construction and installation are intended to accomplish this. *Id.* ¶12.

The most critical characteristic of a clean room is its isolation from the uncontrolled and unknown outside environment. This means the air present in the clean room can enter only after passing through a filtration process. Airborne contaminants in a cleanroom are controlled, reduced, and eliminated through air filtration systems designed to remove the particulate laden air and replace it with filtered air with a significantly smaller concentration of particles or none at all. *Id.*

A well designed cleanroom must be completely enclosed, with all surfaces, joints, ductwork, piping, tubes, and utility access openings sealed to prevent the unwanted entry of contaminants.[5] Any opening in the cleanroom provides a path for particles to enter via airflow into the room or gravitational settling. The slightest of openings creates the risk of viable living particulate contamination entering the cleanroom space.[6]

In particular, ceilings and wall surfaces above work surfaces within the cleanroom must be well sealed to prevent contaminants from entering via the force of gravity or from external ambient pressure changes.[7] For example, ceiling tiles, light fixtures and filters must have a tight seal by securely resting inside of the inverted T shaped ceiling grid. In typical environments where cleanrooms are found, if properly designed and installed, the seal created between the

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[3] *Austin Decl.* ¶11.

[4] *Id.*

[5] *Id.* ¶13.

[6] *Id.*

[7] *Id.*

inverted T shaped bars of the ceiling grid and the light fixture of HEPA filter will prevent contaminants from entering the cleanroom from above.

Airborne contaminants in the cleanroom are also controlled through the use of air pressure that prevents contaminants from entering into the cleanroom. Air filtration systems are designed to maintain the cleanroom at a small positive pressure relative to its exterior environment.[8] Because air moves from an area of high pressure to an area of lower pressure, the higher pressure in the cleanroom pushes clean air out through any openings in the cleanroom enclosure.[9] This outward flow of clean air through any openings inhibits the flow of contaminated air into the cleanroom.

B. Cleanrooms are classified by their intended level of cleanliness.

The standards for classifying cleanrooms stem from the International Organization for Standardization ("ISO").[10] The ISO promotes worldwide industrial and commercial standards. The concentration of particles within a cleanroom is measured and compared to the standard referred to as ISO 14644-1, which defines classes of cleanliness[11] based on the concentration and type of airborne particles within the room.[12]

According to the ISO standard, cleanrooms are certified as meeting the requirements of a particular class if they meet specific criteria. The standard defines limits for the concentrations of particles of various sizes for each of 9 different cleanliness classes: ISO Class 1 through ISO

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[8] *Id.* ¶14.

[9] *Id.*

[10] *Id.* ¶21.

[11] The levels of cleanliness described in ISO 14644-1 were originally developed by one of Plaintiffs' expert consultants, Dr. Philip R. Austin, in conjunction with his original work that led to the publication of Federal Standard 209: the first public standard to define the levels of airborne particulate cleanliness within a cleanroom. Federal Standard 209 was the public standard for defining cleanroom cleanliness for over 30 years, until it was incorporated into ISO 14644-1in 1999.

[12] *Id.* ¶23.

Class 9. Class levels have significant differences in cleanliness. Each decrement of one cleanliness class represents an environment that is ten times cleaner.[13] [14]

C. Applicable ISO standards require testing of any new cleanroom in various stages.

ISO standards include testing and certification standards for a cleanroom under three different states: 1) as built, 2) at rest, and 3) operational.[15] The "as built" state is defined by the condition of the cleanroom after completion of construction, but before the presence of production equipment, product, and personnel within the room at the time of testing. Testing in the "as built" state is designed to demonstrate the performance of a newly constructed cleanroom.[16] This test state assumes further testing will be conducted since subsequent steps will necessarily result in increased particulate contamination. The ISO standard states, "It should be recognized that the 'as-built' state is applicable to newly completed or newly modified cleanrooms or clean zones. Once testing in the 'as-built' state is completed, further testing for compliance *will be performed* in the 'at-rest' or the 'operational' state, or both."[17]

The "at rest" state is defined by the condition of the cleanroom after completion of construction and installation of all production equipment required for normal production activities to be performed within the room. Testing in the "at rest" state is designed to demonstrate the performance of the fully operational cleanroom without the variables of human

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[13] For example, an ISO Class 5 cleanroom is 10 times cleaner than an ISO Class 6 cleanroom and 100 times cleaner than an ISO Class 7 cleanroom. *Austin Decl.* ¶27.

[14] *Id.* ¶27.

[15] *Id.* ¶28.

[16] *Id.*

[17] ISO 14644-1, Section 3.1 attached to the Declaration of Thomas M. Sobol ("*Sobol Decl.*") as Exhibit 1. (*emphasis added*).

activity and active equipment movement within the cleanroom.[18]

The "operational" state is defined by the condition of the cleanroom in its fully operational condition. Testing is performed on a cleanroom during normal production activities with equipment operating during normal production and with personnel present, performing their normal production activities. Testing in the "operational" state is designed to demonstrate the performance of the cleanroom under the same conditions under which production will be performed. This type of testing provides the most accurate and relevant representation of the levels of contamination to which a product will be exposed, and provides the most accurate measure of cleanroom performance as designed and constructed. Testing in the "operational" state allows identification of specific contamination issues that can affect the quality of the product being manufactured within the cleanroom.[19]

D. Applicable ISO standards require the ceiling of a cleanroom to be designed to prevent ingress of contaminants.

The ISO Standards also give guidance on the proper design of cleanroom ceiling systems. ISO 14644-4 states that:

> **E.2.1.2 Ceilings**
> Ceilings should be sealed, to prevent ingress of air bearing particles, or other contaminants, from the ceiling void. Filters, filter frames, filter housings and diffusers mounted in the ceiling should be sealed. Penetration points (e.g. for utility services, sprinklers and lighting) should be kept to the minimum required, and be sealed. Consideration should be given to the location and configuration of components such as lights and sprinklers to avoid disturbance of the intended airflow.[20]

Jeff Erickson, the project "engineer" on the NECC cleanrooms testified in

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[18] *Austin Decl.* ¶28.

[19] *Id.* ¶30.

[20] *Sobol Decl.*, Exhibit 2.

deposition that:

[redacted]

Mr. Erickson further testified that in building a Class 6 Clean Room, [redacted] [22]

E. Liberty designed and installed the 2006 Cleanroom.

Liberty designed and installed three cleanrooms at the NECC Facility, certifying the first on October 7, 2005 (the "2005 Cleanroom,"), the second on July 12, 2006 (the "2006 Cleanroom,") and the third on March 6, 2008 (the "2008 Cleanroom").

The contaminated drugs were compounded exclusively in the 2006 Cleanroom.[23] Liberty provided [redacted] for the 2006 Cleanroom.[24] Liberty's website itself states that "the clean room project must be coordinated from start to finish or disaster may ensue."[25] Mr. Erickson further testified that [redacted] [26]

The 2006 Cleanroom was designed by Liberty as a turbulent flow cleanrooms, with HEPA filters spaced apart on the ceiling surface, and air return plenums at various locations

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[21] Transcript of Deposition of Jeff Erickson dated November 18, 2014 ("*Erickson Dep. Trans.*"), 50:2-8. *Sobol Decl.*, Exhibit 14.

[22] *Id.*, 50:14-18.

[23] See *Sobol Decl.* Exhibit 15.

[24] *Erickson Dep. Trans.*, 141:7-16.

[25] *Id.*, 48:13-18.

[26] *Id.*, 176:18-21.

along the walls and central support pillars.[27] The ceiling grid system of the 2006 Cleanroom was designed to hold the weight of ceiling panels, light fixtures, and HEPA filter modules that together formed the ceiling surface of the cleanroom enclosure.[28]

For the cleanroom to function properly, the ceiling panels, light fixtures, and HEPA filters had to fit together inside the ceiling grid to prevent contaminants from entering the cleanroom from above. *Id.* If using this design, these joints must be reinforced with clips, seals, or other accessories to add an extra level of protection for maintaining an isolated environment. This design, if properly implemented, creates a barrier so contaminants won't go through them.[29] As Mr. Erickson testified [redacted] ,,[30]

III. LEGAL STANDARD

Summary judgment is to be granted only where there is no factual dispute and where the issue may be determined as a matter of law.[31] In ruling upon a motion for summary judgment, the court is to consider all the material designated by the parties including pleadings, affidavits, depositions, and testimony in the light most favorable to the nonmoving party in order to determine whether a genuine issue of material fact remains for resolution by a trier of fact.[32] A genuine issue of material fact exists where facts concerning an issue which would dispose of the litigation are in dispute or where the undisputed facts are capable of supporting conflicting

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[27] *Austin Decl.* ¶ 39.

[28] *Id.* ¶ 40.

[29] *Erickson Dep. Trans.*, 93:24-94:6

[30] *Id.*, 94:2-4.

[31] *Bassett v. Glock*, 174 Ind.App. 439, 368 N.E.2d 18 (1977).

[32] Ind. Trial Rule 56; *Ayres v. Indiana Heights Volunteer Fire Dept., Inc.*, 493 N.E.2d 1229 (Ind. 1986).

inferences on such an issue.[33] If a court has any doubts concerning the existence of a genuine issue of material fact, those doubts must be resolved in favor of the nonmoving party.[34]

Similarly, the Indiana Court of Appeals has noted that "the issues of negligence, contributory negligence, causation, and reasonable care are most appropriately left for determination by the trier of fact."[35] "Proximate cause is primarily a question of fact to be determined by the jury. Therefore, ordinarily, the issue of proximate cause is not properly resolved by summary judgment."[36] Negligence may be proved by direct or circumstantial evidence and circumstantial evidence is sufficient to defeat a motion for summary judgment.[37]

IV. ARGUMENT

The very nature of the building in which the cleanrooms were to be built made them particularly susceptible to infiltration from contamination due to changes in air pressure within the building itself. Changes in air pressure, especially rapid lowering of ambient air pressure in an old warehouse, can cause ceiling tiles to lift out of the ceiling grid, exposing the cleanroom to outside contamination. Liberty admits that when installing the 2006 Cleanroom, it failed to account for the changing air pressure endemic to a warehouse setting such as NECC's facility.

In designing and installing the cleanrooms at NECC, Liberty also utilized subpar designs, issued premature certifications, failed to properly seal the rooms, and installed them defectively, contributing to the contamination of the cleanrooms from outside particles and to the outbreak of fungal meningitis and other injuries in patients in 26 states.

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[33] *Scott v. Bodor, Inc.*, 571 N.E.2d 313 (Ind. App. 1991).

[34] *Woodward Insurance, Inc. v. White*, 437 N.E.2d 59, 62 (Ind. 1982).

[35] *See Crossno v. State*, 726 N.E.2d at 382.

[36] *Sparks v. White*, 899 N.E.2d 21, 29 (Ind. Ct. App. 2008) (citations omitted).

[37] *Shepard v. Porter*, 679 N.E.2d 1383, 1388, (Ind. App. 1997); *Richter v. Klink Trucking, Inc.*, 599 N.E.2d 223, 227 (Ind. App. 1992).

A. When it designed and installed the 2006 Cleanroom, Liberty did not consider the fact that the NECC facility was subject to rapidly changing air pressure that could subject the cleanroom to contamination.

NECC's facility in Framingham was a warehouse. By any measure, the building appeared tired. Because of the shape, design, and failings of the original building, it was susceptible to outside weather conditions such as pressure changes due to ordinary wind patterns.[38]

Dr. Austin explains that in the case of the NECC building, an ambient outside pressure change will cause a rapid and almost instantaneous pressure change in the attic cavity above the top of any constructed cleanroom within the building.[39] The result of these natural changes in pressure is an oscillation in air pressure over the clean room. When the pressure is greater in the space above the cleanroom ceiling, contaminants from the attic space are forced down into the cleanroom through any holes, spaces or gaps in the ceiling that might exist. When the attic pressure is negative in the space above relative to the cleanroom, the cleanroom ceiling panels, lights and filters are lifted up exposing the cleanroom to outside air. The result is what Plaintiffs' experts call a "profuse entrance of contaminants" into the NECC cleanrooms.[40]

Mr. Erickson testified that [redacted].[41] When asked if he could discuss the relationship between outside and internal air pressure in a warehouse such as NECC's, [redacted]"[42] Mr. Erickson's [redacted] Mr. Erickson's education [redacted]

[38] *Austin Decl.* ¶50.

[39] *Id.*

[40] *Id.*

[41] *Erickson Dep. Trans.*, 101:5-9.

[42] *Id.* 101:18-21.

[redacted][43]

At deposition Mr. Erickson did agreed that [redacted][44] [redacted][45]

Although unaware of the potential problem when they designed the 2006 NECC cleanroom, Liberty was made aware of this problem as early as 2008. [redacted]„[46] He goes on to say, "[redacted]„[47] [redacted][48]

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[43] *Id.* 205:19-22.

[44] *Id.* 106:7-12.

[45] *Id.* 101:22-102:7.

[46] *See Sobol Decl.*, Exhibit 3.

[47] *Id.*

[48] *Id.*

Mr. Erickson testified that [redacted] [49] But he testified that [redacted] [50] Mr. Erickson acknowledged "[redacted]"[51] He admits that by design, [redacted] [52] [redacted]"[53]

B. The celling grid in the 2006 Cleanroom was improperly designed and installed by Liberty leaving large gaps through which contamination could enter the cleanroom.

From the start, Liberty failed to properly analyze the setting in which the Cleanrooms were being constructed. Although Mr. Erickson testified that [redacted]"[54] During the installation of the 2005 Cleanroom, Liberty [redacted]. In response to an NECC inquiry, Liberty stated [redacted]

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[49] *Erickson Dep. Trans.*, 118:1-5.

[50] *Id.* 112:6-13.

[51] *Id.* 97:17-19.

[52] *Id.* 125:10-16.

[53] *Id.* 168:21-169:4.

[54] *Id.* 90:12-15; 91:20-92:2.

[redacted]"[55] The evidence shows Liberty's initial decision to place a clean room in a dirty building and dirty environment was made under the erroneous assumption that there was no substantial risk of contamination present from above. [redacted][56]

Mr. Erickson testified that [redacted] When asked why not, [redacted]."[57] [redacted].[58] This carelessness is worsened by his admissions that [redacted]"[59]

In December of 2012, the PSC's experts inspected the Liberty designed and installed cleanrooms at NECC. Based on that inspection, Dr. Austin has concluded that the ceiling system of the 2006 Cleanroom was improperly designed and installed by Liberty in 2006. Large gaps were present between the light fixtures and the ceiling grid and similar large gaps were present between some of the HEPA filters and the ceiling grid. Plaintiffs' expert has concluded that the gaps and holes observed in the ceiling of the 2006 Cleanroom existed at the time the cleanroom

[55] *Sobol Decl.*, Exhibit 4.

[56] *Erickson Dep. Trans.*, 120:16-121:11.

[57] *Id.*, 92:6-14.

[58] *Id.*, 93:12-16.

[59] *Id.*, 105:17-22.

was installed. There is no evidence that there was any intervening work done to the ceiling by NECC between the installation of the 2006 Cleanroom and the 2012 inspection that would have caused the gaps to appear.[60]

The images below, taken from on top of the 2006 Cleanroom, shows light shining from below in the cleanroom itself through significant gaps between the ceiling grid and a number of different light fixtures:

[60] *Austin Decl.* ¶¶ 41-48.


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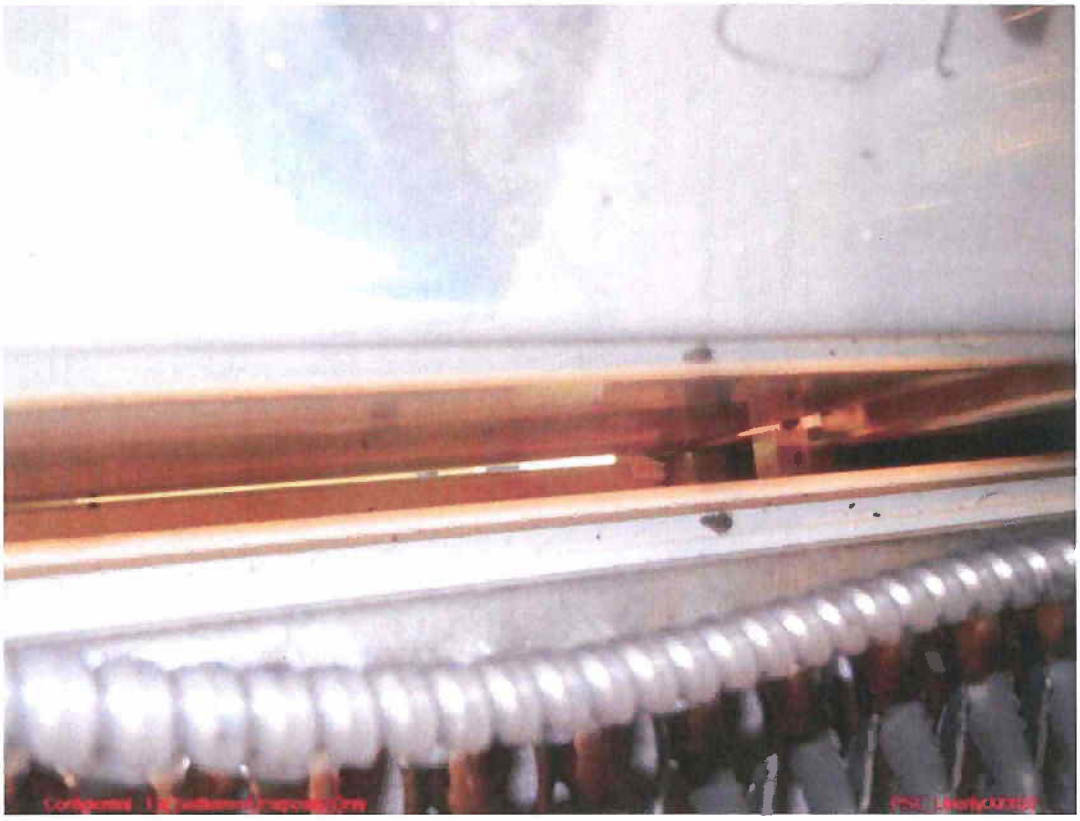
21



Gaps between the grid and some of the filters and light fixtures were large enough to push a pencil through. One filter unit, depicted in the image below, was observed to have a gap larger than 1/4" wide at its widest point, running the length of the HEPA filter on two sides, between its perimeter and the ceiling grid. When viewed from above the ceiling, one could look directly down into the cleanroom below.[61]

[61] *Id.* ¶ 43.

These gaps allowed contaminants to rain down into the cleanroom through both open unrestricted airflow and gravitational settling. Worst of all, the largest observed gap was directly above an area in which it is believed that compounding of contaminated drugs was performed and significant debris was observed adjacent to the gap, on top of the HEPA filter and adjacent lights and ceiling tiles.[62]

[62] *Id.* ¶ 44

In order for the ceiling to properly function as a barrier from contaminants entering into the cleanroom, the entire perimeter of the light fixture or filter must seal against the gasket in the grid, with no gaps or holes through which particles can enter into the cleanroom below.[63] No amount of positive pressure within the cleanroom could mitigate the effect of these imperfections in the cleanroom design and construction.[64] This is especially true given the oscillating pressures present in the attic space due to the inherent structural characteristics of the NECC facility.[65] While positive pressure can provide resistance to the flow of contaminated air into the cleanroom, the positive pressure is only effective to the extent that the induced air flow can

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[63] *Austin Decl.* ¶ 43.

[64] *Id.* ¶ 47.

[65] *Id.* ¶ 49-50.

support the weight of any given particle.[66]

For particles of larger size or greater density, the positive pressure airflow provides insufficient force to prevent entry of these particles into the cleanroom. In the case of the defects that were observed in the 2006 Cleanroom, the holes were large and provided direct access to particles from gravitational settling. The amount of positive air flow through these openings, even under optimal conditions, would be insufficient to resist larger particles of solid debris or liquid droplets from entering into the cleanroom.[67] The size and types of particles that were observed resting on the exterior surfaces of the ceiling panels, filters, and light fixtures would not be prevented from entering into the cleanroom by the positive pressure effect.[68]

The fact that some of these gaps were observed adjacent to the HEPA filter modules means that the positive pressure effect would have been reduced or even reversed due to entrainment of the surrounding air by the air being discharged from the HEPA filter.[69] As the air flows out of the HEPA filter, the air adjacent to the filter is drawn into the air stream. This creates a circulation pattern in the area adjacent to the filter.

This circulation pattern creates a slight negative pressure along the ceiling surface next to the filter, as the air along the ceiling surface is being sucked into the flow of air being discharged from the filter (entrained). This phenomenon is known as the Venturi effect.[70] The slight negative pressure draws contaminated air into the cleanroom through the gap, mixing it with the clean air being discharged from the HEPA filter.[71] Based on Plaintiffs' expert's observation of

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[66] *Id.* ¶ 47.

[67] *Id.*

[68] *Id.*

[69] *Id.* ¶ 48.

[70] *Id.*

[71] *Id.*

some of the HEPA filters, it is likely that such entrainment of contaminants was occurring in the main area of the cleanroom, drawing contaminated air into the cleanroom through these unsealed openings in the ceiling precisely where the medications were being produced.[72]

C. The gaps observed in the 2006 Cleanroom existed as installed by Liberty and were not the result of any subsequent work performed by NECC

Based on the size and appearance of some of these gaps in the ceiling, Plaintiffs' expert has concluded these defects were present as a result of the initial installation of the ceiling system.[73] Liberty has provided no evidence and nothing was observed to suggest that any modifications to the ceiling had been made in these areas since its installation.[74]

Plaintiffs' expert opines that the very design of the ceiling would have made it extremely difficult for such modifications to result in the formation of these gaps without a complete replacement of the entire ceiling.[75] Dr. Austin opines that the gaps in the ceiling were systemic based on an improper alignment of the fixed grid elements which made it impossible to seal the affected grid openings with the materials (lights, filters, and ceiling panels) designed to rest inside of the openings to seal against the grid.[76] In other words, the grid opening designed and installed by Liberty to receive the light fixtures or HEPA filters were too large to allow for a tight seal around the fixtures. Even if there were evidence that for instance a HEPA filter module was later adjusted after installation of the ceiling (and there is none), it would have been impossible to position the filter in the grid without the presence of a gap between the filter and

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[72] *Id.*

[73] *Austin Decl.* ¶ 45.

[74] *Id.*

[75] *Id.*

[76] *Id.*

the grid.[77] Simply put, Liberty designed and installed the grid improperly leaving spaces where there should have been none.

D. Liberty prematurely and improperly certified the 2006 Cleanroom.

Liberty represented that it would provide NECC with an ISO 6 cleanroom "certified as built, prior to installation of customer supplied equipment in strict accordance with ISO Standard 14644-1."[78] Despite its claims to the contrary in its Motion, Liberty failed to perform this obligation. While the 2006 Cleanroom was still being built on July 12, 2006, Liberty authorized its certification "at rest," not "as built" as was promised in its November 21, 2005 proposal to NECC. "At rest" is a more stringent condition than "as built," "where installation is complete with equipment installed and operating in a manner agreed upon by the customer and supplier, but with no personnel present."[79] Most importantly, under the ISO Standards, "as-built" certification requires additional testing, whereas "at rest" does not. Thus, Liberty knowingly used the wrong certification method, when the cleanroom had not yet reached the "as built" condition, and in doing so avoided any future obligation for certification as required by ISO14644-1 (Section 3.1) and as promised by them to their customer.

Numerous documents and correspondence between the NECC and Liberty establish that the parties contemplated the completion of certain work prior to certification. Liberty maintained Percentage of Completion & Schedule of Construction sheets defining when certain unfinished or uncommenced tasks were to be completed. [redacted]

[77] *Austin Decl.* ¶ 45.

[78] Sobol Decl., Exhibit 5.

[79] *Sobol Decl.*, Exhibit 1, 2.4.2.

[redacted][81]

On July 10, 2006, just two days prior to the scheduled certification, Liberty conveyed to NECC that it felt as though [redacted]."

[redacted][82]

[redacted]"[83] ISO 14644-1 does not allow these types of defects to remain when performing "as built," let alone "at rest" certification of a cleanroom. Liberty *knowingly* allowed for the certification of a cleanroom that was not complete even after acknowledging access points (exposures) for contamination and in violation of industry standards.

The following day, July 11, 2006, one day before Liberty's certification of the 2006 Cleanroom, [redacted].[84]

[redacted]

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[80] *Sobol Decl.*, Exhibits 6 and 7.

[81] *Sobol Decl.*, Exhibit 8.

[82] *Sobol Decl.*, Exhibit 9.

[83] *Id.*

[84] *Sobol Decl.*, Exhibit 10.

[redacted][85] [redacted]

On July 12, 2006, the 2006 Cleanroom passed the minimum requirements for an ISO Class 6 clean zone in an "at rest" occupancy state based on the following tests: HEPA Filter Leak Test, Velocities, Air Supply Volumes, and Particle Counts.[86] The tests which Liberty performed do not necessarily mean that a cleanroom is suitable.[87] These tests do not account for the risk of contamination by falling particles, nor do they consider the type of particles that are present in the environment.

[redacted][89] No supplemental certification was provided after the additional work was performed. [redacted] With this knowledge and after having been paid for its work, Liberty washed its hands of the 2006 Cleanroom.

Despite Liberty's attempt to blame NECC for the improper certification of the 2006 Cleanroom,[90] Mr. Erickson admitted at his deposition [redacted]

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[85] *Id.*

[86] *Sobol Decl.*, Exhibit 11.

[87] *Austin Decl.* ¶ 52.

[88] *Sobol Decl.*, Exhibit 12.

[89] *Sobol Decl.*, Exhibit 13.

[90] Liberty Brief, Dkt. 1472, page 6.

[redacted][1][redacted]

[redacted]

[redacted],,92

E. Plaintiffs have met their burden of proof by providing evidence that establishes Liberty breached its duty to Plaintiffs.

Much of Liberty's Motion is predicated on an erroneous conclusion that Plaintiffs have provided no evidence that Liberty did anything wrong with respect to the NECC cleanrooms.[93] Plaintiffs have established that Liberty breached its duty to Plaintiffs.[94] Liberty's failure to account for the change in pressure endemic to a warehouse facility such as NECC, their failure to properly design and install the ceiling grid in the 2006 Cleanroom to avoid gaps, and their improper and premature certification of the 2006 Cleanroom all evidence Liberty's breach of duty. Plaintiffs' expert has opined that Liberty's failures were a proximate cause of the fungal contamination in NECC's cleanroom.[95] Plaintiffs have demonstrated that a triable issue of fact exists as to the question of Liberty's breach, and Liberty's Motion should be denied.

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[91] *Erickson Dep. Trans*, 131:17-21.

[92] *Id.*, 131:17-132:4.

[93] Liberty Brief, Dkt. 1472, page 10

[94] Liberty has not directly argued that it had no duty to Plaintiffs, merely that it breached no duty to Plaintiffs. Liberty's duty to Plaintiffs is clear. See *Sampson v. Honeywell Int'l Inc.*, 547 Fed. Appx. at 379, (where the defendant contracted to clean a leased railway car, they owed a duty to clean the car to the standard enumerated in the contract. In *Sampson,* the defendant leased a railway car, which they used to transport dangerous refrigerant gas, from General American Transportation Corporation ("GATX"). *Id.* at 370. In the lease agreement, defendants agreed to return the car "cleaned of commodities" to the degree that "the car is safe for human entry." *Id.* The defendant cleaned the inside of the car and tested the levels of dangerous gas, allegedly receiving an acceptable result. *Id.* at 371-72. The plaintiff, an employee of GATX who was not a party to the contract, entered the interior of the leased car, was "overcome by the hazardous environment," and ultimately died. The court found that the defendant owed the third party plaintiff a duty to service the cleaning of the car to the standard of "safe for human entry." The Court held that there was a dispute of material fact as to whether the defendant failed to exercise reasonable care in undertaking its duty and whether it "should have known" that its cleaning service was necessary for the protection of third parties, like the plaintiff. *Id.* at 379. The court held that the dispute of material facts on the two issues were questions for the jury and reversed the lower court's granting of summary judgment for the defendant on the two issues. *Id.*

[95] *Austin Decl.* ¶¶ 56-57.

F. The ability of the 2006 Cleanroom to pass subsequent air quality tests does not absolve Liberty of liability.

Liberty argues that subsequent testing of the cleanroom according to the requirements of ISO 14464-1 proves that the cleanroom was properly functioning.[96] Testing for airborne particulates in accordance with ISO 14464-1 is only one factor in establishing that a cleanroom is properly functioning according to its intended purpose. Equally important, if not more important, is the requirement that the cleanroom is properly constructed and maintained.[97] If a pile of dirt was sitting in the corner of a cleanroom, it certainly would not be suitable for the compounding of drugs, yet, according to Liberty's argument the cleanroom would be acceptable by its standards as long as it passed ISO 14464-1 air quality testing. The fact that the cleanroom was never in an acceptable state, due to the gaps in the ceiling, means that no amount of maintenance would have made the cleanroom suitable for the compounding of drugs. While poor maintenance practices by NECC might have contributed to the contamination event it does not absolve Liberty for its role in constructing a cleanroom in which contaminants could fall through the ceiling into the area in which the drugs were compounded. Indeed, where a duty to a third party arises by virtue of a contract and/or undertaking, a defendant is not relieved of liability to those third parties simply because the other party was also negligent.[98] Liberty likewise, is not relieved from its liability to Plaintiffs because of NECC's conduct.

G. Plaintiffs have met their burden of proof by providing evidence that Plaintiffs' injuries are the natural and probably consequence of Liberty's breach.

Liberty argues that there is no evidence Liberty's breach was the proximate cause of

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[96] Liberty Brief, Dkt. 1472, p. 11-12.

[97] *Austin Decl.* ¶ 52.

[98] *See e.g., St. Clair v. B&L Paving Co.*, 270 Pa. Super. 277, 280 (Pa. Super Ct. 1979) (court found where defendant created a dangerous condition it could not avoid its duty by citing the negligence of another).

Plaintiffs' injuries.[99] Proximate cause is primarily a question of fact to be determined by the jury.[100] The issue of proximate cause is ordinarily not properly resolved by summary judgment.[101] "An act or omission is said to be a proximate cause of an injury if the resulting injury was foreseen, or reasonably should have been foreseen, as the natural and probable consequence of the act or omission."[102]

The very reason international standards for the construction of cleanrooms exist is because contamination of the products manufactured within a cleanroom is a natural and proximate consequence of the failure to properly construct a cleanroom. ISO 14644-4 establishes the specific requirements for the materials of construction and design of a cleanroom. It requires ceilings and wall systems to be completely sealed to prevent ingress of unwanted particles into a cleanroom.[103] There simply can be no question that contamination of the type that occurred in this case is a natural and probable consequence of Liberty's failure to properly seal the ceiling of the 2006 Cleanroom.

Liberty argues that if it were in fact Liberty's breach that caused the contamination of the three MPA lots, it is probable that more than three batches of drugs would have been contaminated.[104] Plaintiffs' expert explains that this argument demonstrates a lack of understanding of cleanrooms and how contamination occurs. It is precisely the fact that the contamination occurred on only a few occasions which supports the conclusion that the defects

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[99] Liberty Brief, Dkt. 1472, p. 13.

[100] *Rhodes v. Wright*, 805 N.E.2d 382, 388 (Ind. 2004); *Sparks v. White*, 899 N.E.2d 21, 29 (Ind. Ct. App. 2008).

[101] *Hendrick v. Tabbert,* 722 N.E.2d 1269, 1273 (Ind. Ct. App. 2000).

[102] *Funston v. Sch. Town of Munster*, 849 N.E.2d 595, 600 (Ind. 2006).

[103] *Austin Decl.*, ¶33.

[104] Liberty Brief, Dkt. 1472, p. 13.

in the cleanroom ceiling were the likely source of the fungus contamination in the cleanroom.[105] It is likely that the contamination was intermittent and coincided with debris falling on top of the cleanroom ceiling, changes in the building air pressure, or vibrations which could move particles from on top of the ceiling through the gaps in the ceiling.[106] The degree and magnitude of the contamination entering the cleanroom would likely have varied significantly over time, and worsened as the cleanroom aged, as more debris collected above the ceiling.[107]

H. Liberty's argument that NECC's modifications to the cleanroom and failure to observe good cleanroom practices are superseding and intervening causes fail.

Defendants argue that NECC's subsequent modifications to the 2006 Cleanroom and their failure to properly clean and practicing safe compounding techniques were intervening causes which absolve Liberty of any liability for its breach.[108] These arguments fail both as a matter of the facts and as a matter of law.

First, with respect to NECC's supposed modifications, Plaintiffs' expert opines that the gaps observed in the ceiling of the 2006 Cleanroom were the result of poor design and/or poor installation on the part of Liberty, not a result of any subsequent modifications. Dr. Austin opines that in order to create the gaps observed in the ceiling NECC would have had to remove and replace the entire cleanroom ceiling.[109] There is no evidence of any kind that this was done. The ceiling grid is the same today as when it was designed and installed by Liberty in 2006 and

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[105] Austin Decl. ¶54.

[106] *Id.*

[107] *Id.*

[108] Liberty Brief, Dkt. 1472, p. 14-15.

[109] *Austin Decl.* ¶ 45.

the gaps created by Liberty's defective design and installation were not caused by any subsequent modifications.

Second, Liberty's breach is also not excused by NECC's alleged failure to properly clean. Negligent conduct by NECC does not discharge Liberty of its liability to the Plaintiffs for its own wrongdoing. It is well-established that when there are two or more contributing causes for injuries sustained, the causation requirement is satisfied for each defendant if each "owe[d] concurrent duties to the injured party, [then] each may be liable for breach of their respective duty."[110] As such, Liberty's conduct need not be the only cause of injuries in order for it to be liable to the victims of this outbreak.[111]

Furthermore, NECC's actions cannot be considered an intervening cause that breaks the causal link between the Plaintiffs' injuries and Liberty, because NECC's conduct was reasonably foreseeable. If the claimed intervening cause is reasonably foreseeable, the original tortfeasor cannot escape liability.

> A negligent act or omission is the proximate cause of an injury if the injury is a natural and probable consequence which, in light of the circumstances, should reasonably have been foreseen or anticipated, regardless of whether the earlier negligence concurs with other proximate causes of injury or whether another act of negligence intervenes. . . . If the actor should have realized his conduct might cause harm to another in substantially the manner in which it is brought about, the harm is universally regarded as the legal consequence of the actor's negligence. If the intervening cause is foreseeable, the original tort-feasor cannot escape liability.[112]

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[110] *National R.R. Passenger Corp. v. Everton by Everton*, 655 N.E.2d 360, 366 (Ind. Ct. App. 1995).

[111] *Id.; See also Ingersoll-Rand Corp. v. Scott*, 557 N.E.2d 679, 684 (Ind. Ct. App. 1990) (acts of negligence need not be the sole proximate cause of the injury in order for liability to arise.)

[112] *McKinney v. Public Service Co.*, 597 N.E.2d 1001 at 1005-1006 (Ind. Ct. App. 1992) (internal citations omitted); *Bloomington v. Kuruzovich*, 517 N.E.2d 408 (Ind. Ct. App. 1987); *Humphery v. Duke Energy Ind., Inc.*, 916 N.E.2d 287 (Ind. Ct. App. 2009); *Ousley v. Board of Commissioners of Fulton County*, 734 N.E.2d 290 (Ind. Ct. App. 2000).

It was completely foreseeable that contamination might infiltrate the cleanroom through the gaps left by Liberty's faulty design and installation of the cleanroom ceiling. It was also completely foreseeable that whatever contamination might infiltrate the cleanroom from above might not be cleaned in time or sufficiently to eliminate the possibility it would find its way into the pharmaceutical products being compounded in the room below. If these things were not foreseeable, there would be no need for stringent international regulations on the building, maintenance, and cleaning of cleanrooms.

I. CONCLUSION

For the reasons set forth above, Plaintiffs ask the Court to deny Liberty's motion for summary judgment.

Dated: December 22, 2014

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Thomas M. Sobol, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: December 22, 2014

/s/ Thomas M. Sobol
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